K121955

Section 4 - 510(k) Summary

Administrative Information and Device Identification

DEC 14 2012

Name and address of the manufacturer and sponsor of the 510(k) submission:	Manufacturer: Respironics, Inc. 175 Chastain Meadows Court Kennesaw, GA 30144-3714 Office: (770) 423-2322 Fax: (770) 423-2300 Sponsor: Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-7562 Fax: 724-387-7490
FDA registration number of the manufacturer of the new device:	Manufacturer: 1040777 (Establishment registration number) Sponsor: 2518422 (Establishment registration number)
Official contact person for all correspondence:	Colleen Witt, RAC Senior Regulatory Affairs Engineer Philips Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-4870 Fax: 724-387-7490 Email: colleen.witt@philips.com
Date Prepared:	June 29, 2012
Device Name:	Philips Respironics CoughAssist T70
Proprietary name of new device:	Philips Respironics CoughAssist T70
Common or usual name of the device:	Secretion Clearance Device
Philips/Respironics model number:	Philips Respironics CoughAssist T70
Classification of new device:	Class II
Classification of the predicate device:	Class II
Classification Panel:	Anesthesiology
Panel Code:	NHJ – noncontinuous ventilator (IPPB)

CFR Regulation Number:	21 CFR 868.5905 a) *Identification.* A noncontinuous ventilator (intermittent positive pressure breathing – IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. (b) *Classification.* Class II (performance standards).
Predicate Device Name(s) and 510(k) numbers:	Emerson CoughAssist, Model CA-3000 – K002598 Dima Italia Negavent DA-3 Plus Pegaso - K072292
Reason for submission:	Device modifications

Description of Device

The Philips Respironics CoughAssist T70 is a portable electric device which utilizes a blower and a valve to apply alternating positive and then a negative pressure to a patient's airway in order to assist the patient in clearing retained bronchopulmonary secretions by simulating a cough. It includes a means to adjust the pressure and suction levels applied, a pressure gauge to measure the pressures, and a means (optional) to reduce the positive pressure (inhale) flow. The air is delivered to and from the patient via a breathing circuit incorporating a flexible tube, a bacterial filter and either a facemask, a mouthpiece or an adapter to a tracheostomy or endotracheal tube.

Like its predicates, the Respironics CoughAssist T70 device is for use on any adult or pediatric patient unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. Operators of the device are expected to be patients, lay caregivers (family members), clinicians, home nurses, homecare provider technicians, physicians and service personnel. The environment of use for the device will be for use in the hospital, institutional environment or in the home.

The CoughAssist T70 device is designed to deliver a cough cycle to a patient. A cough cycle includes a positive pressure inhale phase, a negative pressure exhale phase and a near zero pressure pause phase.

The CoughAssist T70 engineering design incorporates closed loop control algorithms through the motor controller and valve controller software algorithms. Block diagrams and a stability analysis have been provided for these closed loop algorithms.

The motor and valve controller utilize PID controllers. The PID gains are empirically tuned to achieve the necessary response and stability of the system to give best performance for all patient cases identified in the Product Requirements Document (provided in Attachment A of

the original submission). Additionally, adaptive gain changes are implemented in the Valve Controller to reject any external disturbance and to account for process and condition changes.

The CoughAssist T70 Valve (Pressure) Control system is designed to maintain stability throughout the operating flow range of the device. This includes steady-state stability with open and occluded patient circuit as well as disturbance rejection stability in cases where the device rapidly transitions from high flow to no flow and back to high flow again (open patient circuit to occluded patient circuit back to open patient circuit). Additionally, when in the inhale and exhale phases, the device pressure is continuously monitored to ensure that the pressure being delivered is the same polarity as the set point pressure. In the event of extreme flow rates (if the patient becomes disconnected from the device during therapy), the motor and valve controllers are designed to avoid any controller instability.

If the device is in Auto mode, the device will continuously trigger and cycle. If CoughTrak is enabled, the device will stay in the Pause phase waiting for the patient to trigger (which will not happen if the patient is not connected). In the Pause phase, the pressure is limited in order to minimize flow; a standby state is provided to preserve motor operation.

Statement of Intended Use

The Respironics CoughAssist T70 assists patients in clearing retained bronchopulmonary secretions by gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure. This rapid shift in pressure, via a facemask, mouthpiece or an endotracheal or tracheostomy tube, produces a high expiratory flow rate from the lungs, simulating a cough.

Indications for Use

The Respironics CoughAssist T70 is intended for use on adult or pediatric patients unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.

Comparison of Device Technological Characteristics to Predicate Device

Substantial Equivalence

The Respironics CoughAssist T70 device has the following similarities to the previously cleared predicate devices:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

The table below summarizes the key technical characteristics between the CoughAssist T70 to those of the predicate devices listed in the submission:

Technological Characteristic	**Description**	**Emerson CoughAssist**	**Negavent DA-3 Plus Pegaso**
Patient Population	Adult or pediatric patient unable to cough or clear secretions effectively	Adult or pediatric patient with an ineffective cough due to muscular dystrophy, myasthenia gravis, poliomyelitis, or other neurologic disorder with some paralysis of the respiratory muscles, such as spinal cord injury.	Adult or pediatric patient unable to cough or clear secretions effectively
Delivery Type	Non Invasive or Invasive	Non Invasive or Invasive	Non Invasive or Invasive
Modes of Operation	Manual and Auto	Manual and Auto	Manual and Auto
Inhalation Pressure	0 to 70 cmH_2O	0 to 60 cmH_2O	+5 to 70 cmH_2O
Exhalation Pressure	0 to -70 cmH_2O	0 to -60 cmH_2O	-5 to -70 cmH_2O
Inhale Flow	Low, Medium, High	Low and High	Low, Medium, High
Pause Time	0 to 5 seconds	0 to 5 seconds	0.1 – 9.9 seconds
Phases of Therapy Cycle	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause
Therapy Features	CoughTrak	N/A	N/A
CoughAssist, including CoughTrak Safety Protocols	Dynamic Stability Analysis Flow and Pressure Based Oscillation Detection Extreme Flow Rate Control and Response Sensor Malfunction Stability	N/A	N/A
Remote Data Access	A secure digital (SD) card provides means for data access	N/A	N/A

The table below provides a description of the modifications to the Respironics CoughAssist T70 device that are the subject of this 510(k) submission:

Device Modification	Description
User Interface	A new graphical user interface with hierarchal menu system
Delivered Pressure	The device Inhale pressure is 0 to 70 cmH_2O and Exhale pressure is 0 to -70 cmH_2O
CoughTrak	A feature for patients who can provide a spontaneous breathing effort to trigger the cough sequence, instead of using manual or auto modes of therapy. This software feature monitors the device outlet pressure and initiates the Insufflation phase of therapy delivery when the pressure decreases below a set threshold indicative of patient effort.
Displayed Therapy Parameters	The device displays outlet pressure, measured peak cough flow and measured inhaled tidal volume
Data Management	Therapy data will be stored on an SD card, which will be compatible with both DirectView and Encore
Oximetry Accessory	Device shall interface with the Oximetry accessory to display current SpO_2 and heart rate data received from the oximeter
Wired Remote Control	A remote control accessory (foot pedal) is provided to initiate manual therapy by means of a wired remote control interface
External Suctioning Accessory Interface	Device shall provide a DC output intended to power an external suctioning accessory
Power Management	Options include a Detachable battery, External DC battery and Universal Battery pack

The software design and algorithm descriptions for each of these modifications to the CoughAssist T70 device have been provided as part of this 510(k) submission.

Performance Data

Non-Clinical Testing

Black-box performance testing was conducted for the CoughAssist T70 device using side by side bench testing methodologies to demonstrate that the CoughAssist T70 device performs to design input specifications and is equivalent to the predicate device. This bench testing included both open and closed loop conditions from the defined patient test cases to verify that the CoughAssist T70 software algorithms performed to specification. Bench testing conducted for the CoughAssist T70 device characterized the types of worst case scenario inputs that would be experienced in the intended use environment such as extreme flow rates. Additional white-box testing verified proper operation under conditions of sensor malfunctions and inaccurate or complete sensor dropout. This combination of testing demonstrated that the CoughAssist T70 closed loop control algorithms function safely and effectively under worst case scenarios.

Device Modification Testing Summary

Verification activities have been performed to verify that the device modifications stated above did not affect the safety and effectiveness of the subject device. This included bench testing, software unit testing and code reviews.

The table below provides a summary of the testing that was conducted on the modifications to the Respironics CoughAssist T70 device that are the subject of this 510(k) submission:

Device Modification	**Testing Summary**
User Interface including displayed therapy parameters	Has been verified to meet product requirements defined for the CoughAssist T70 UI. Bench testing, code reviews and software unit testing was performed to ensure that all display functions, user controls and informational messages performed as intended. The User Interface was verified to ensure that it displayed the proper data and expected therapy information.
Delivered Pressure and Flow Stability	Verification testing has verified that the CoughAssist T70 device delivers accurate pressure for the intended duration of the insufflation, exsufflation and pause phases of therapy. The CoughAssist T70 has been verified to demonstrate pressure and flow stability across all patient test cases, including extreme flow rates and sensor malfunctions (i.e. sensor inaccuracies and / or complete sensor drop out).
CoughTrak	The CoughTrak feature of the CoughAssist T70 device has been verified to meet product specifications with each defined patient case simulation. The availability, operation and triggering performance has been verified to operate across the range of patient cases.
Data Management	Data management of the CoughAssist T70 device has been verified to meet product specifications for SD card data integrity. Software verification, including code reviews and software verification testing was conducted to verify the expected results with the SD card.
Oximetry Accessory	The Oximetry Accessory has been tested to verify the behavior of the pulse oximetry data and the proper display of data received by the oximetry accessory.
Wired Remote Control	Verification testing has been conducted to verify the availability and operation of the CoughAssist T70 wired remote control device.
External Suctioning Accessory Interface	The CoughAssist T70 device has been verified to demonstrate that the device provides power to a suctioning accessory as specified.
Power Management	The CoughAssist T70 has been verified to properly interface with the detachable battery, properly display the battery information, properly charge the battery and indicate a low battery charge. The CoughAssist T70 has also been verified to be compatible with an external DC power supply, to properly display the power supply information and to properly indicate a low external battery.

Standards Evaluation

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The Respironics CoughAssist T70 device was designed and tested according to:

1. ISO 14971 Medical devices – Application of risk management to medical devices

2. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

3. IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements of Safety

4. IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility

5. IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: Usability

6. IEC 60068 Environmental Testing (Part 2-6, 2-27, 2-64): Mechanical Vibration and Shock Resistance testing

7. IEC 62304 Medical device software – Software life cycle processes

The CoughAssist T70 device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993); and

- FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

As suggested by FDA's November 1993 publication entitled "Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices" the Respironics CoughAssist T70 device was tested in accordance with the applicable voluntary standards. The Respironics CoughAssist T70 met the required performance criteria and functioned as intended.

Conclusion

The CoughAssist T70 modifications that are the subject of this 510(k) submission have been validated using non-clinical tests and have been determined to be substantially equivalent. In summary, bench testing (black-box and white-box) and software code reviews have confirmed that the CoughAssist T70 device performs equivalently to the cited predicate devices. The indications for use, technological characteristics, and principles of operation are similar to the predicate devices. The Respironics CoughAssist T70 device is substantially equivalent to the predicate devices and the device, as changed, does not raise any new issues of safety and effectiveness.

Respironics CoughAssist T70 (K121055)			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		page 1		
	Submitter' s name, address, phone #, a contact person		page 1		
	Date the summary was prepared		page 1		
	The name of the device/trade name/common name/classification name		page 1		
	An identification of the legally marketed Predicate		page 2		
	Description of the subject device		page 2-3		
	Statement of intended use(identical to indications for use)_		page 3		
	Technological characteristics	if same, a summary of comparison of technological characters	page 4		
		If different, a summary of how do they compare to the Predicate	page 4		
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	page 5-7		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			X
		Conclusion that data demonstrate SE	page 7		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 14, 2012

Ms. Colleen Witt, RAC
Senior Regulatory Affairs Engineer
Respironics, Incorporated
1740 Golden Mile Highway
MONROEVILLE PA 15146

Re: K121955
Trade/Device Name: Philips Respironics CoughAssist T70 Device
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: October 31, 2012
Received: November 1, 2012

Dear Ms. Witt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA 2012.12.14 15:34:55 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6.0 Indications for Use

Indications for Use

510(k) Number (if known): K121955

Device Name: Philips Respironics CoughAssist T70 device

The Philips Respironics CoughAssist T70 is intended for use on adult or pediatric patients unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
2012.12.14 15:41:43 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121955